

EXHIBIT 4

*Redacted Version of Document
Provisionally Filed Under Seal*

HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

PLEXXIKON INC.,)	
)	
Plaintiff,)	
)	
v.)	
)	
NOVARTIS PHARMACEUTICALS)	
CORPORATION,)	
)	
Defendant.)	

C.A. No. 4:17-CV-04405-
HSG (EDL)

SUPPLEMENTAL EXPERT REPORT OF GREGORY K. LEONARD, PH.D.

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I. INTRODUCTION AND ASSIGNMENT

1. My name is Gregory K. Leonard. I am an economist and partner at Edgeworth Economics, 333 Bush Street, Suite 1450, San Francisco, CA, 94104.

2. On February 4, 2019 I submitted the Expert Report of Dr. Gregory K. Leonard, which I incorporate in this supplemental report. I have been asked by counsel for Plexxikon to supplement my calculations of Plexxikon’s damages due to Novartis’ alleged infringement of Plexxikon’s U.S. Patent Nos. 9,469,640 and 9,844,539 to account for new information that Novartis has produced since the submission of my report, and to prepare this supplemental report to present my calculations and results. I reserve the right to further supplement or render further opinions as additional information becomes available.

3. I understand that Novartis produced data on its U.S. sales of Tafenlar[®] and Mekinist[®] from January 2018 through December 2018.¹ In my initial report, I was unable to exactly determine Novartis’ U.S. sales of Tafenlar[®] during 2018. To account for the new information in my calculation of Plexxikon’s reasonable royalty damages, I have updated my analyses to reflect Novartis’ actual U.S. sales of Tafenlar[®] during 2018. An updated set of my Exhibits and Appendices are attached.

II. CALCULATION OF REASONABLE ROYALTY DAMAGES


4. [REDACTED]

[REDACTED] See Supplemental Exhibit 1. To calculate reasonable royalty damages, I apply a range of royalty rates that Plexxikon and Novartis may have agreed to in a

¹ NPC-PLEX012797176, NPC-PLEX012797177, NPC-PLEX012797178, NPC-PLEX012797179.

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hypothetical negotiation to the appropriate royalty base.² I have applied rates based on the Collaboration Agreement as described in my expert report, of 6.26% and 12.52%, depending on if the value of patent rights are given relatively lower or higher weight, resulting in damages of [REDACTED] respectively.³


Gregory K. Leonard

Dated: February 21, 2019

² I have also calculated damages of \$21.95 million based on Plexxikon’s minimum willingness to accept.

³ Supplemental Exhibit 1.

Appendix B

Supplemental Appendix B Documents Considered

Bates Documents

NPC-PLEX0000003	NPC-PLEX012036518	NPC-PLEX012182774	NPC-PLEX012388611
NPC-PLEX0000927	NPC-PLEX012041509	NPC-PLEX012205332	NPC-PLEX012389705
NPC-PLEX0000942	NPC-PLEX012069416	NPC-PLEX012383702	NPC-PLEX012390487
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PXK0022396	PXK0023386	PXK0026677	PXK0148920
G-PKN00021058	G-PKN00021059		

Depositions

Deposition of Ahmed Elnawawi and Exhibits, November 20, 2018.
 Deposition of Bijoyesh Mookerjee and Exhibits, December 4, 2018.
 Deposition of Kathy Glaub, February 1, 2019 (rough).
 Deposition of Peter Waibel and Exhibits, November 13, 2018.
 Deposition of Robert Gleason and Exhibits, November 19, 2018.
 Deposition of Tara Rhealt and Exhibits, December 18, 2018.

Expert Reports & Interviews

Conversation with Dr. Michael Metzker.
 Conversation with Dr. Susana Ortiz-Urda, Dermatologist and Melanoma Specialist.
 Conversation with Joe Young, Plexxikon VP of Finance.
 Conversation with Kathy Glaub, former President of Plexxikon.
 Conversation with Mark Dennish, Former Vice President, Business Development at Daiichi Sankyo.
 Expert Report of Dr. Michael Metzker, February 4, 2019.
 Expert Report of Dr. Susana Ortiz-Urda, February 4, 2019.
 Expert Report of Ted Sweeney, February 4, 2019.

Court & Legal Documents

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Tsai, J., et al., “Discovery of a selective inhibitor of oncogenic B-Raf kinase with potent antimelanoma activity,” Proceedings of the National Academy of Sciences USA, February 26, 2008, 105(8): 3041–3046, published online February 19, 2008, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2268581/>.

“Two new GSK oral oncology treatments, BRAF-inhibitor Tafinlar®(dabrafenib) capsules and the first MEK-inhibitor Mekinist™ (trametinib) tablets, approved by FDA as single-agent therapies,” GSK, May 29, 2013, <https://us.gsk.com/en-us/media/press-releases/2013/two-new-gsk-oral-oncology-treatments-braf-inhibitor-tafinlardabrafenib-capsules-and-the-first-mek-inhibitor-mekinist-trametinib-tablets-approved-by-fda-as-single-agent-therapies/>.

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U.S. Patent No. 9,469,640.

U.S. Patent No. 9,844,539.

Exhibits

Supplemental Exhibit 1
Reasonable Royalty Damages

October 18, 2016 - December 31, 2018

	<u>Q4 2016¹</u>	<u>Q1 2017</u>	<u>Q2 2017</u>	<u>Q3 2017</u>	<u>Q4 2017</u>	<u>2018</u>	<u>Total</u>
	(a)	(b)	(c)	(d)	(e)	(f)	(g)
U.S. Tadalafil® Sales	\$ 29,198,083	\$ 33,158,192	\$ 39,477,867	\$ 40,448,738	\$ 43,062,275	\$ 211,660,369	\$ <u>397,005,524</u>
Total U.S. Tadalafil® Sales	\$ 397,005,524						
Royalty Base Lump Sum Deduction ²	19,850,276						
Royalty Base	\$ 377,155,248						

Scenario 1 - Collaboration Agreement Low Range

Royalty Rate	6.26 %
Total Damages	\$ 23,606,684

Scenario 2 - Collaboration Agreement High Range

Royalty Rate	12.52 %
Total Damages	\$ 47,213,367

Notes: Scenarios 1 and 2 are based on the Collaboration Agreement, as discussed in section V.B.2.e of my expert report.

¹ Q4 2016 is prorated to the date of the hypothetical negotiation, October 18, 2016.

² Consistent with the Collaboration Agreement, royalties are paid on sales (net of returns, rebates and discounts) less a 5% lump sum deduction. See PXX0006148 at 6160.

Sources: Exhibit 2a.
Exhibit 5a.
Expert Report of Dr. Gregory Leonard, February 4, 2019.
NPC-PLEX012797179.
PXX0006148.

[REDACTED]

[REDACTED]

[REDACTED]

Exhibit 3

Plexxikon's Minimum

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

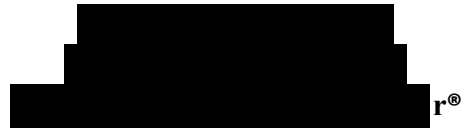
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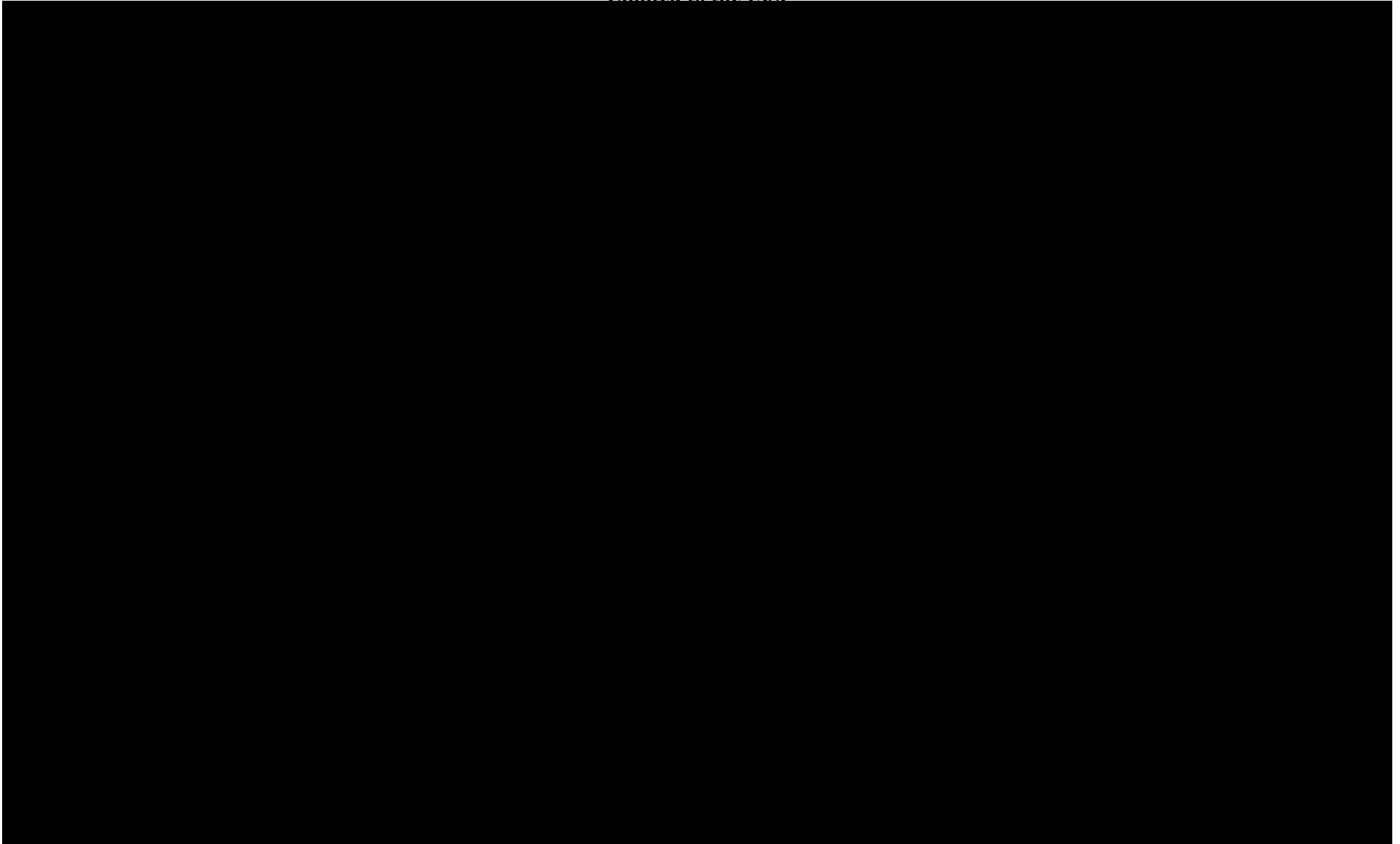
[REDACTED]

[REDACTED]

Sources: NPC-PLEX0003644.
NPC-PLEX012386879.
NPC-PLEX012390487.
P XK0006148.
P XK0006709.
P XK0020416.
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Cowen and Company, Array BioPharma, "Initiating at Outperform: Array of Sunshine + CowenVision Video,"
November 4, 2016.
Cowen and Company, Roche Holding Ltd, "KOLs View ACE910 Safety Issues As A Potential Concern;
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September 26, 2016.



Limited to the U.S.



Notes:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Sources:

Supplemental Exhibit 1.

Supplemental Exhibit 6.

Exhibit 7.

NPC-PLEX0004666.

PXK0006148.

PXK0020416.

PXK0028126.

ClinicalTrials.gov Identifiers: NCT00880321; NCT01153763; NCT01227889; NCT01336634; NCT01682083; NCT01682213; NCT02034110.

NDA Approval Letter from Richard Pazdur, M.D., Department of Health and Human Services, to Ellen Cutler, GlaxoSmithKline, LLC, NDA 202806, May 29, 2013, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/202806Orig1s000ltr.pdf.

Pharmacology Review, Application Number: 202806Orig1s000, Center for Drug Evaluation and Research, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/202806Orig1s000PharmR.pdf.

Supplemental Approval Letter from Patricia Keegan, M.D., Department of Health and Human Services, to Betsy Kurian, Pharm.D., Novartis Pharmaceuticals Corporation, NDA 202806/S-010, May 4, 2018, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/202806Orig1s010ltr.pdf.

Supplemental Approval Letter from Patricia Keegan, M.D., Department of Health and Human Services, to Demetre Stamatis, Pharm.D., Novartis Pharmaceuticals Corporation, NDA 202806/S-006, June 22, 2017, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/202806Orig1s006ltr.pdf.

Supplemental Approval Letter from Patricia Keegan, M.D., Department of Health and Human Services, to Demetre Stamatis, Pharm.D., Novartis Pharmaceuticals Corporation, NDA 202806/S-008, April 30, 2018, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/202806Orig1s008ltr.pdf.

The diagram illustrates a network structure with 5 columns and 5 rows of nodes. The nodes are represented by black squares. The connections and annotations are as follows:

- Row 1:** All nodes are connected to a single horizontal line above them. The first node is also connected to a vertical line on its left, which is part of a larger structure on the far left.
- Row 2:** All nodes are connected to a single horizontal line above them. The first node is also connected to a vertical line on its left, which is part of a larger structure on the far left.
- Row 3:** All nodes are connected to a single horizontal line above them. The first node is also connected to a vertical line on its left, which is part of a larger structure on the far left.
- Row 4:** All nodes are connected to a single horizontal line above them. The first node is also connected to a vertical line on its left, which is part of a larger structure on the far left.
- Row 5:** All nodes are connected to a single horizontal line above them. The first node is also connected to a vertical line on its left, which is part of a larger structure on the far left.

Additional annotations include:

- A large black square on the far left, spanning the first two rows.
- A large black square on the far left, spanning the third and fourth rows.
- A large black square on the far left, spanning the fifth row.
- A large black square on the far left, spanning the first two rows.
- A large black square on the far left, spanning the third and fourth rows.
- A large black square on the far left, spanning the fifth row.

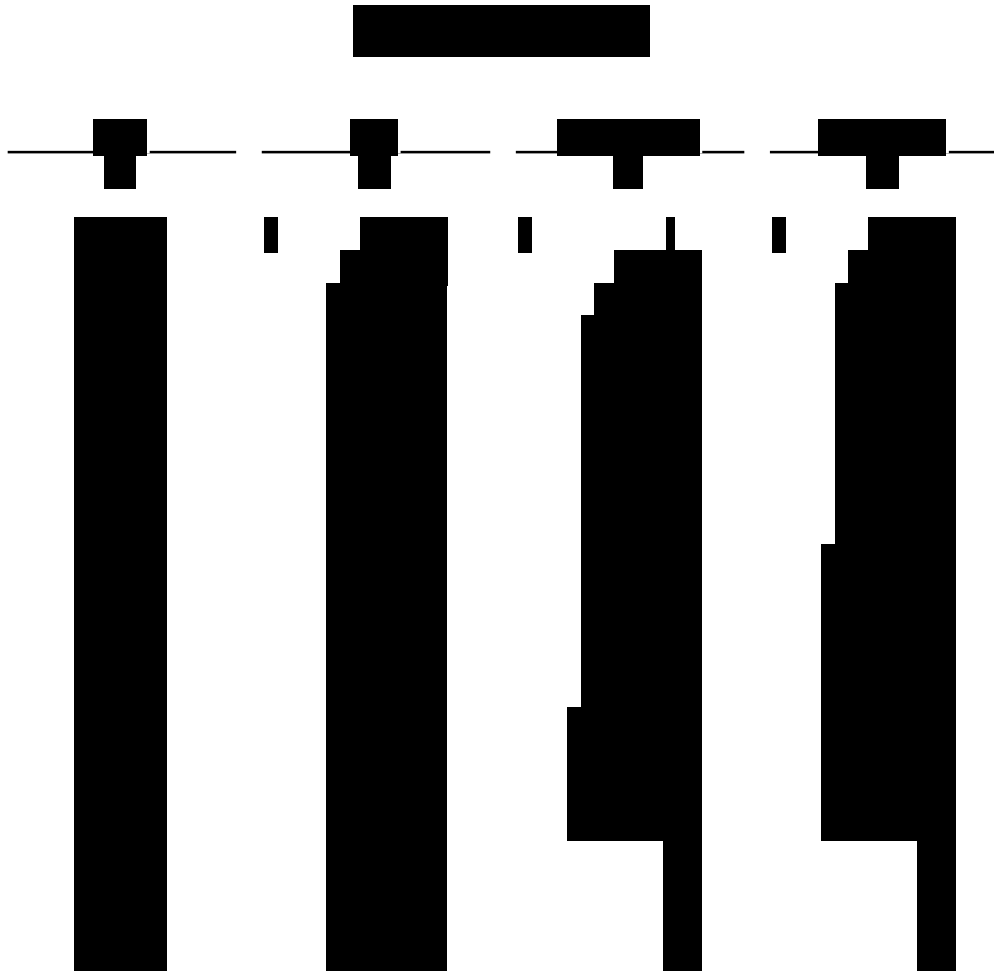
Source: NPC-PLEX0003644.

Source: NPC-PLEX012390487.

[REDACTED]
 [REDACTED]
 [REDACTED]

Sources: Exhibit 5a.
Exhibit 5b.

Supplemental Exhibit 6
Tafinlar® Sales



[Redacted text block]

Sources: Exhibit 5a.
Exhibit 5b.
NPC-PLEX012797179.
NPC-PLEX0004666.

Exhibit 7
Zelboraf® Sales

Q3 2011 - Q3 2018

Date	U.S.	Outside U.S.	Worldwide
(a)	(b)	(c)	(d)
Q3 2011	\$ 11,963,838	\$ -	\$ 11,963,838
Q4 2011	22,071,522	-	22,071,522
Q1 2012	28,965,650	1,987,686	30,953,337
Q2 2012	31,963,972	25,774,018	57,737,990
Q3 2012	27,248,263	30,068,844	57,317,108
Q4 2012	31,673,353	40,746,550	72,419,904
Q1 2013	33,930,608	51,809,818	85,740,426
Q2 2013	36,308,832	51,895,633	88,204,465
Q3 2013	31,361,062	59,534,795	90,895,857
Q4 2013	30,196,971	67,854,142	98,051,113
Q1 2014	20,373,347	63,253,216	83,626,563
Q2 2014	19,545,520	59,427,835	78,973,355
Q3 2014	18,376,578	58,514,077	76,890,654
Q4 2014	14,159,605	51,115,255	65,274,861
Q1 2015	12,241,358	40,937,842	53,179,200
Q2 2015	11,308,343	38,506,209	49,814,552
Q3 2015	12,729,470	38,645,667	51,375,136
Q4 2015	10,036,751	39,202,450	49,239,202
Q1 2016	11,878,075	38,442,020	50,320,095
Q2 2016	11,291,460	42,070,002	53,361,462
Q3 2016	12,394,318	33,323,226	45,717,544
Q4 2016	12,543,216	32,701,601	45,244,816
Q1 2017	11,324,743	31,411,000	42,735,743
Q2 2017	10,304,038	26,166,973	36,471,011
Q3 2017	10,325,506	23,998,742	34,324,248
Q4 2017	10,799,558	24,308,943	35,108,501
Q1 2018	11,076,261	29,723,351	40,799,612
Q2 2018	12,339,426	26,072,030	38,411,456
Q3 2018	12,757,720	21,848,921	34,606,642

Note: Zelboraf® received FDA approval in August 2011 and sales began in Q3 2011.

Sales are net of returns, rebates, and discounts.

Sources: P XK0006688-P XK0006710.

P XK0006720.

P XK0006722.

P XK0148906.

P XK0020353.

P XK0021909.

P XK0028283.